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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,213	08/05/2003	David Haffner	GLAUKO.011CP1	6863

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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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05/13/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/634,213	Applicant(s) HAFFNER ET AL.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7-9,11,27,28,37 and 53-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,7-9,11,27,28,37 and 53-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a complete response to the amendment filed October 6, 2008.
2. Claims 5, 7-9, 11, 27, 28, 37, and 53-76 are currently pending.

Specification

3. The Examiner acknowledges the amendments to the abstract, title, and specification filed October 6, 2008.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 5, 7-9, 11, 27, 28, 37, and 53-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,544,249) in view of Lynch et al. (US 6,464,724) and Paraschac et al. (US 6,050,999). Yu et al. disclose the invention substantially as claimed including an instrument and method for delivering implants for treating an ophthalmic condition. The instrument comprises an elongate body comprising a tube (32) having a cutting edge (40; col 6, ll 56-57), a trocar (36) in the tube having a cutting edge (col 7, ll 10-15) sufficiently sharp to cut through the wall of Schlemm's canal, and a biocompatible implant (10) positioned inside the elongate body with the trocar passing through the lumen of the implant (Fig 2), and an actuator (34) for dispensing the implant. The implant comprises a cutting member and is shaped and sized to convey aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye so as to reduce elevated intraocular pressure (Fig 1). The method of using the device

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comprises inserting the instrument into the eye through an incision (Figs 3-8) and delivering the implant through a wall of Schlemm's canal at a first collector channel location. The cutting member of the trocar (36) pierces eye tissue and the implant (10) is advanced over the trocar to the first location through a trabecular meshwork of the eye (Figs 5-6).

However, Yu et al. does not disclose the method comprises delivering a plurality of implants. Lynch et al. disclose a similar method for treating an ocular disorder including inserting an instrument into an eye through an incision, utilizing the instrument to deliver a first implant (100) through a wall of Schlemm's canal (30) at a first location, and utilizing the instrument to deliver a second implant (100) through a wall of Schlemm's canal at a second location (Figure 5; col 6, ll 41-50). Lynch et al. teach the locations are at collector channels (55). When implanted, the implants convey aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye (col 4, ll 57-63). Specifically, Lynch et al. teach, "placement of multiple stents [implants] within Schlemm's canal can result in near circumferential traverse of Schlemm's canal" (col 6, ll 45-46). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Yu et al. such that multiple implants were delivered, without removing the instrument from the eye between deliveries, to create additional flow channels and improve the flow of aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye and thereby further reduce intraocular pressure in more severe cases. Furthermore, Paraschac et al. discloses a device for delivering a plurality of ocular implants (40), wherein the implants are arranged end to end within an elongate tubular member (Fig 9C) and the actuator (61) comprises a separator (59) to serially dispense the implants in a controlled manner (col 6, ll 45-61).

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Therefore, it would have been obvious to modify the combination of Yu et al. and Lynch et al. such that the multiple implants were arranged end to end within the tube to be dispensed serially by the actuator in a controlled manner.

Regarding claims 27 and 70, it is old and well known in the art to use imaging techniques throughout surgical procedures to identify target locations and monitor the placement of devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the locations of the implants were determined by imaging collector channel locations.

Regarding claims 28 and 73, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that first and second implants were spaced at least 20 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPQ 215). Furthermore, it would have been obvious to try placing the first and second implants at least 20 degrees apart since it is obvious to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success.

Regarding claim 71, it is old and well known in the art to use a superiorly located limbal incision to access the eye in ocular surgeries. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the a superiorly located limbal incision was made to deliver the implants, as ocular surgeons are familiar with the surgical technique for such an incision and the technique is known to be safe and effective.

Regarding claims 74-76, Yu et al. do not disclose the implant is placed in the uveal scleral outflow path of the eye. Lynch et al. teach aqueous humor is normally drained out of the eye through two different routes: "In the "uveoscleral" route, the fluid percolates between muscle fibers of the ciliary body. This route accounts for approximately ten percent of the aqueous outflow in humans. The primary pathway for aqueous outflow in humans is through the "canalicular" route that involves the trabecular meshwork and Schlemm's canal" (col 1, ll 35-48). Therefore, it would have been obvious to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the first and second locations were in the uveal scleral outflow path of the eye as the uveal scleral outflow path of the eye is a well known normal anatomical drainage location and is a known alternative to the trabecular meshwork outflow path of the eye if the implant is unable to be implanted through the trabecular meshwork in a particular patient.

Response to Arguments

6. Applicant's arguments with respect to claims 5, 7-9, 11, 27, 28, 37, and 53-76 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Katherine Dowe
May 10, 2009

/K. M. D./
Examiner, Art Unit 3734